Docket No.: 294828US68PCT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: GROUP: 1611

Kazuhiko KATOU, et al.

SERIAL NO: 10/589,658 EXAMINER: WELTER, RACHAEL E.

FILED: August 16, 2006

FOR: TOOTHPASTE COMPOSITION

## **DECLARATION UNDER 37 C.F.R. § 1.132**

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes Kazuhiko Kato who deposes and states:

- 1. That I am a graduate of the Graduate School of Ibaraki University, Materials Science and Engineering, and received my master's degree in the year 1992.
- 2. That I have been employed by Kao Corporation, for 19 years, involved in research and development for analytical science from 1992 to 1994 and then involved in research and development of oral products from 1994 to present.
- 3. That I understand the English language or, at least, that the contents of the Declaration were made clear to me prior to executing the same.
- 4. That the following experiments were carried out by me or under my direct supervision and control.
- 5. A representative number of test compositions according to the invention, which satisfy Equation (1) (wt. % of (B) water x 0.3 + 25 ≤ (wt.% of (A) erythritol) and comparative compositions not satisfying this Equation(1) were prepared from water and erythritol in the proportions described in Table 1 below.

- 6. The refreshing /cooling qualities of each composition were evaluated in a manner similar to that represented in paragraph [0031] in the present specification, except that three volunteer was evaluated according to the standards A, B, C and D described below and the evaluation score shown in Table 1 as the judgment result indicates that evaluated by two or more volunteers.
- A: The toothpaste was obviously superior in refreshed feeling to the reference toothpaste, which is equal to the evaluation result of A or B represented in paragraph [0031] of the present specification.
- B: The toothpaste was a little superior in refreshed feeling to the reference toothpaste, however, inferior to that scored evaluation A represented above.
- C: Erythritol was slightly present in powder form and the toothpaste was equal to the reference toothpaste.
- D: Erythritol was completely dissolved.

Table 1

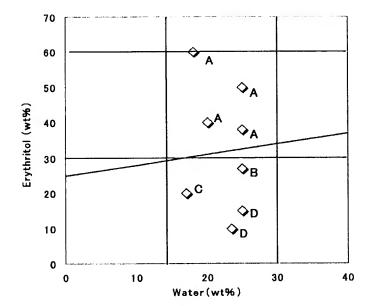
|   | Ref.  | Ex. 1' | Ex. 2' | Ex. 3' | Ex. A | Comp.<br>Ex. 1 | Comp.<br>Ex. 2 | Comp.<br>Ex. 3 | Com.<br>Ex. 4 |
|---|-------|--------|--------|--------|-------|----------------|----------------|----------------|---------------|
| Erythritol  |       | 40     | 50     | 60     | 38    | 10             | 17             | 15             | 27            |
| Water   | 20    | 20     | 25     | 18     | 25    | 23.5           | 20             | 25             | 25            |
| Xylitol   |       |        |        |        |       |                |                |                |               |
| Glycerin  | 14    | 14     | 0      | 0      | 14    | 14             | 14             | 14             | 14            |
| Sorbitol  | 46.99 | 6.99   | 5.99   | 2.99   | 3.99  | 33.49          | 29.99          | 26.99          | 14.99         |
| Sodium Carboxymethylcellulose                     | 1.2   | 1.2    | 1.2    | 1.2    | 1.2   | 1.2            | 1.2            | 1.2            | 1.2           |
| Xanthan gum                                       | 0.05  | 0.05   | 0.05   | 0.05   | 0.05  | 0.05           | 0.05           | 0.05           | 0.05          |
| Saccharin sodium                                  | 0.05  | 0.05   | 0.05   | 0.05   | 0.05  | 0.05           | 0.05           | 0.05           | 0.05          |
| Sodium fluoride                                   | 0.21  | 0.21   | 0.21   | 0.21   | 0.21  | 0.21           | 0.21           | 0.21           | 0.21          |
| Sodium lauryl sulfate                             | 1.5   | 1.5    | 1.5    | 1.5    | 1.5   | 1.5            | 1.5            | 1.5            | 1.5           |
| Abrasive silica                                   | 10    | 10     | 10     | 10     | 10    | 10             | 10             | 10             | 10            |
| PEG   | 5     | 5      | 5      | 5      | 5     | 5              | 5              | 5              | 5             |
| Flavor  | 1     | 1      | 1      | 1      | 1     | 1              | 1              | 1              | 1             |
| Total amount                                      | 100   | 100    | 100    | 100    | 100   | 100            | 100            | 100            | 100           |
| Cooling sensation                                 | -     | Α      | Α      | Α      | Α     | D              | С              | D              | В             |
| Conforms to Equation (1)? (see values in Table 2) | No    | Yes    | Yes    | Yes    | Yes   | No             | No             | No             | No            |

- 7. Also, the properties of each test and comparative composition were evaluated according to the standards A, B, C and D described below.
- A: Erythritol is present in powder form and excellent cooling sensation is obtained, which is equal to the evaluation result of A or B represented in paragraph [0031] of the present specification.
- B: Erythritol is present in power form, however, the cooling sensation is inferior to that scored evaluation A represented above.
- C Erythritol is hardly present in powder form and cooling sensation is not obtained.
- D Erythritol is dissolved and cooling sensation is not obtained.
- 8. Table 2 shows the effects of selecting compositions that conform to equation (1) according to the invention.

Table 2

|             | Water (wt.%) | Erythritol (wt.%) | wt. % of (B) water x 0.3 + 25 | Satisfies Equation (1) ? | Evaluation |
|-------------|--------------|-------------------|-------------------------------|--------------------------|------------|
| Ex. 1       | 20           | 40                | 31                            | Yes (31 < 40)            | Α          |
| Ex. 2       | 25           | 50                | 32.5                          | Yes (32.5 < 50)          | Α          |
| Ex. 3       | 18           | 60                | 30.4                          | Yes (30.4 < 60)          | Α          |
| Comp. Ex. 2 | 17           | 20                | 30.1                          | No                       | С          |
| Comp. Ex. 3 | 25           | 15                | 32.5                          | No                       | D          |
| Comp. Ex. 1 | 23.5         | 10                | 32.05                         | No                       | D          |
| Comp. Ex. 4 | 25           | 27                | 32.5                          | No                       | В          |
| Ex. A       | 25           | 38                | 32.5                          | Yes (32.5 < 38)          | Α          |

9. The figure below maps the compositions shown in Table 2. The samples according to the invention fall within the upper-mid box between 15-30 wt.% water and 30-60 wt.% erythritol. Each of these samples in the upper box was evaluated as imparting an excellent cooling sensation "A". The comparative samples in the mid-lower box that did not conform to Equation (1) produced inferior or no cooling sensation. Equation (1) appears as a diagonal line intersepting the Y axis at 25.



- 10. As mentioned above, a composition satisfying Equation (1) includes therein erythritol in powder form and had an excellent cooling sensation.
- 11. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.
  - 12. Further deponent saith not.

(OSMMN 11/10)

|   | Kazuhiko Kato |  |
|---|---------------|--|
|   | Signature     |  |
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